Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

Quality of Life Subcommittee

February 10, 2000

Points to Consider

Session I: Definitional issues across the continuum of patient-centered outcomes

- To what extent do disease-related symptoms overlap with health-related quality of life outcomes?

- In the regulatory setting, quality of life instruments are often proposed to measure outcomes that are compared across treatment arms of a randomized controlled clinical trial. What amount of information regarding instrument validation and performance should be available prior to their use in such studies? What is a minimally-acceptable pre-study justification/rationale for the selected question(s)? What can be done within or parallel to the trial to support the measurement or interpretation?

Session II: Clinical significance/ clinical interpretation

- What are optimal and minimally-acceptable responsiveness data (e.g., effect size; statistical significance testing, etc) that could be used to assess group comparisons?

- What are acceptable clinical or statistical approaches for assessing the magnitude of change in individual measurements?

- Discuss the amount of supporting evidence (e.g., from calibration or estimation methods, etc) that would be sufficient to allow clinical interpretability of questions and summary scores.

Session III: Data Analysis

- What are the strengths and weaknesses of the major types of analytic approaches, i.e., longitudinal modeling vs. univariate techniques (e.g., time to event analysis, AUC, ANOVA)?

- What analytic approaches should be taken to assess the type of missing data (informative vs. non-informative) and handle them in the analysis (e.g., various data imputation techniques, pattern mixture model, etc)?